UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/315,116	05/19/99	ANTELMAN	D 16930-0010-2

020350 HM12/0705
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER	
DAVIS,M	
ART UNIT	PAPER NUMBER
1642	8

DATE MAILED: 07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/315,116	Antelman et al
Examiner	**Art Unit**
Minh-Tam Davis	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 9, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-37* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Applicant's response to the restriction requirement of the Office action of 10/04/2000, paper No: 4 is acknowledged.

After review and reconsideration, claims 1-37 require new restriction.

It is noted that the generic linking claim 16 is improper, because different members of the claims are patentably distinct and thus not linked to each other. That is 1) different functional growth suppression domains of retinoblastoma polypepides are structually distinct, and are patentably distinct and thus not linked to each other, 2) Claim 16 comprises different method steps that are not related to each other, i.e. admnistration of a polypeptide versus administration of a nucleic acid, or gene therapy, and treatment of a disease, with or without the step of angioplasty.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 16, 18-30, 37, drawn to a method for treating cancer, comprising administering a fusion protein comprising a DNA binding domain of a transcriptional factor and a functional growth suppression domain of a retinoblastoma (RB) polypeptide, classified in class 514, subclass 2.

II. Claims 16, 17-30, 37, drawn to a method for treating a hyperproliferative disorder, comprising administering a nucleic acid encoding a fusion protein comprising a DNA binding

domain of a transcriptional factor and a functional growth suppression domain of a retinoblastoma (RB) polypeptide, classified in class 514, subclass 44.

III. Claims 16, 29, 31-33, 37, drawn to a method for treating restenosis, comprising administering after angioplasty, a fusion protein comprising a DNA binding domain of a transcriptional factor and a functional growth suppression domain of a retinoblastoma (RB) polypeptide, classified in class 514, subclass 2.

IV. Claims 16, 17, 34-37, drawn to a method for treating a hyperproliferative disorder, comprising administering, after angioplasty, a nucleic acid encoding a fusion protein comprising a DNA binding domain of a transcriptional factor and a functional growth suppression domain of a retinoblastoma (RB) polypeptide, classified in class 514, subclass 44.

In addition, upon the election of any of groups I-IV, further election of the following patentably distinct species of the claimed invention is required:

Amino acid residues 95 to 286 of SEQ ID NO:1, or amino acid residues 95 to 194 of SEQ ID NO:1.

Upon the election of any of groups I-IV, further election of the following patentably distinct species of the claimed invention is required:

RB polypeptide from amino acid residue 379 to 928 of SEQ ID NO:4, or RB polypeptide having any one of the substitution at residue 2, 608, 612, 788, 807 or 811.

2. The inventions are distinct, each from the other because of the following reasons:

The methods of groups I-IV are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success. Further, the methods of groups (I-II) and (III-IV) are distinct, because the methods of groups III- IV have an additional step of angioplasty.

The species amino acid residues 95 to 286 of SEQ ID NO:1, or amino acid residues 95 to 194 of SEQ ID NO:1 are patentably distinct, because they are structurally different.

The species RB polypeptide from amino acid residue 379 to 928 of SEQ ID NO:4, and RB polypeptide having any one of the substitution at residue 2, 608, 612, 788, 807 or 811 are distinct, because they are structurally distinct..

Because these inventions are distinct for the reason given above and have acquired a separate status in the art as shown by their different classification, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wesnesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

June 20/2001

SUSAN UNGAR, PH.D
PRIMARY EXAMINER